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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/248,178	02/09/1999	STEVEN G. REED	210121.446C2	8493

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EXAMINER

SHEINBERG, MONIKA B

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/248,178

Applicant(s)

REED ET AL.

Examiner

Monika B Sheinberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31, 34-42, 45-52 and 89-106 is/are pending in the application.
- 4a) Of the above claim(s) 1-31, 34-42 and 45-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 89-106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-31, 34-42, 45-52 and 89-106 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Attachment*.

DETAILED ACTION***Response to Amendment E***

Applicants' arguments, filed 12 February 2002, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-31, 34-42, 45-52 and 89-106 are pending. Claims 1-31, 34-42 and 45-52 remain withdrawn. Claims 89-106 are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 89-106, as necessitated by the newly added claims, is maintained under U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 89-106 all include primers and/or probes which are "specific" to the elected SEQ ID NOs: 55, 59-65, and 67. These sequences, beyond exact complementarity and lengths of the elected SEQ ID NOs, are included but not disclosed as to written description. These include oligonucleotide primers that are at least 10 to 15 contiguous nucleotides in length. The sequences identified (by SEQ ID) per se meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 89-106 are directed to encompass DNA gene sequences, and fragments of sequences ("oligonucleotide primers of at least 10 contiguous nucleotides" lines 6-7) of the provided sequences, corresponding sequences from other species, mutated fragment sequences, allelic variants, splice variants, and so forth. None of these additional sequences meet the written description provision of 35 USC 112, first paragraph. The

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specification provides insufficient written description to support the genus encompassed by the claim. Thus applicants' arguments are non-persuasive.

Claims 89-106 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPA 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

The instant application fails to provide guidance to one of ordinary skill in the art for diagnosing breast cancer. The specification discloses on page 31, an example that discloses analyzed results showing over-expressed levels in the breast tumor cDNA library with low levels of expression in "all normal tissues tested" (line 27). This demonstrates that the sequences and their oligonucleotide primers were present to some degree in all samples. Due to detection in all samples, the sequences and their primers are not diagnostic of breast cancer unless elevated levels of expression are observed. The claims read that detection, or "presence" (i.e. claim 89, line 9) of the specified primers in any sample will result in the detection of breast cancer. The claims do not reflect the expression levels disclosed in the specification. Detection or amplification alone do not provide statistically significant information.

In addition, as per the applicants' disclosure of the degree of specificity required, "at least about 60%" (page 28, lines 21-24). The sequences of the prior art disclosed below, as oligonucleotide primers, are 100% specific at various lengths greater than 10 and 15 contiguous

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nucleotides in length. The claims do not require that the biological sample be of breast tissue, thus they read upon any biological sample, including for example a hair sample. The prior art demonstrates that oligonucleotide primers of the elected sequences are detected in non-specific tissue and species; for example prostate, colon, lung, along with species such as plant, rat, swine, etc. The following are some examples: (Please see the attached packet of sequence alignment search results of commercial databases for more examples).

- SEQ ID NO: 55; accession # AA003705 (22-Jul-1996), a sequence of a mouse (total fetus) has 23 contiguous nucleotides with 100% similarity.
- SEQ ID NO: 59; US Patent 6,261,562 (with *common inventors*; filed 09-Feb-1998), sequence 73 of the prostate has 325 contiguous nucleotides with 100% similarity.
- SEQ ID NO: 60; WO 9818931 (22-May-1998), a sequence of *Streptococcus pneumoniae* has 17 contiguous nucleotides with 100% similarity.
- SEQ ID NO: 61; US Patent 6,239,264 (filed 24-Dec-1997), sequence 136 of fungi has 68 contiguous nucleotides with 100% similarity.
- SEQ ID NO: 62; US Patent 5,770,366 (filed 29-Jul-1994), a sequence of a Melanoma-inhibiting protein has 18 contiguous nucleotides with 100% similarity.
- SEQ ID NO: 63; WO 9835693 (20-Aug-1998), a sequence of a secreted protein has 21 contiguous nucleotides with 100% similarity.
- SEQ ID NO: 64; WO 9316178 (19-Aug-1993), a sequence of the brain has 27 contiguous nucleotides with 100% similarity.
- SEQ ID NO: 65; US Patent 6,210,883 (filed 18-Mar-1998), sequence 27 of the lung has 319 contiguous nucleotides with 100% similarity.
- SEQ ID NO: 67; WO 9505457 (23-Feb-1995), a sequence of *Oryza sativa* has 21 contiguous nucleotides with 100% similarity.

Thus as discussed before the claimed methods are not diagnostic of breast cancer. The examples provided are only a generic description of the claimed method. In addition to the fact that no specific type of breast cancer is disclosed. Tumorous breast cancer still does not indicate what kind the cancer is. It appears the methods are claiming diagnostic abilities of any and all breast cancers. While working examples are not, per se, required, the specification must provide

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adequate guidance such that one of skill in the art could practice the invention without undue experimentation. Given the lack of descriptive working examples in the specification, and the unpredictability of diagnosing breast cancer, the specification, as filed is not enabling for the method of using the elected sequences nor the specified oligonucleotide primers as claimed.

Conclusion

Therefore, the arguments are non-persuasive to overcome the rejections. No claim is allowed.

Inquiries

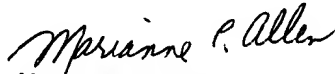
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 3, 2002

Monika B. Sheinberg
Art Unit 1631



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